UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,451	08/21/2003	Joseph L. Bryant	4115-150 CIP DIV	7909

23448 7590 05/20/2008
INTELLECTUAL PROPERTY / TECHNOLOGY LAW
PO BOX 14329
RESEARCH TRIANGLE PARK, NC 27709

EXAMINER	
NOBLE, MARCIA STEPHENS	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
05/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/645,451	BRYANT ET AL.	
	Examiner	Art Unit	
	MARCIA S. NOBLE	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 April 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): 35 U.S.C. § 112, second paragraph.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-11*.
   Claim(s) withdrawn from consideration: *12-21*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.

12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). 1/24/2008

13. ☐ Other: _____.

/Deborah Crouch, Ph.D./
Primary Examiner, Art Unit 1632

Continuation of 11. does NOT place the application in condition for allowance because:
Enablement
Claims 1-11 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant further traverses this rejection. Applicant asserts that the post-filing art of Keppler et al (Exhibit A) demonstrates that the specification is enabling of the instant invention because Keppler et al teaches a double transgenic rat for hCD4 and hCCR5 whose T-cells, macrophages, and microglia are susceptible to infection by HIV-1 R5 viruses and are produced by crossing the single transgenic rats for CD4 and CCR5 in the manner disclosed by the specification (remarks, p. 4, par 2). Applicant's argument is not found persuasive. Keppler et al recapitulates that the art of producing a small animal model for HIV-1 infection was unpredictable because acquiring infectivity was problematic (p. 719, col 1 and 2, p. 720 col 1 through par 1). Keppler discloses a means to overcome some of the unpredictability because Keppler discloses that the vectors to produce both the hCD4 and hCCR5 transgenic rats were modified in a manner to ensure expression in the T cells and in cell from monocyte/macrophage lineage (p. 721, col 1, par 1 of Materials & Methods). These modifications were not disclosed in the specification and therefore the methods of Keppler and the specification would not be considered the same. Furthermore, the specification does not provide specific guidance on the production of a transgenic hCCR5 and only discloses that the double transgenic rat can be made by crossing a hCD4 rat with a hCCR5 rat. Therefore, because Keppler et al confirms the unpredictability of the art and demonstrates a post-filing improvement to produce a double transgenic hCD4/hCCR5 rat with HIV-1 infectivity that was not disclosed in the specification, the art of Keppler et al in fact demonstrates that at the time of filing the invention was made amidst an unpredictable art and that the specification did not provide the specific guidance necessary to overcome these unpredictabilites in the art. Applicant asserts that the art of Reid et al supports the instantly disclosed invention (p. 4, par 2). Applicant's argument is not found persuasive because Reid et al of Exibit B discloses an HIV trangenic rat and does not disclose a double transgenic rat expressing hCD4 and hCCR5. In view of Kessler the production of a transgenic rat for HIV is not sufficient to support allegations of enablement. Therefore, Reid et al is not enabling for the instantly claimed invention. Applicant asserts that the art of Goffinet et al which teaches the use of the hCD4/hCCR5 transgenic rat of Keppler et al for identification of anti-HIV drug demonstrates the enablement of the instantly claimed transgenic rat. This argument is not found persuasive because as discussed above, the transgenic rat taught by Keppler et al only enables the claimed transgenic rat post-filing and therefore demonstrates that the specification is not enable at the time of filing. Postfiling art can support enablement as long as no modifications to the disclosure occurs. In this case Keppler disclosed such modifications. Therefore, because Applicant's arguments are not found persuasive, and Applicant did not amend the claims to address the issues of enablement, the instant enablement rejection is maintained.

New Matter
Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Amended claim 1 recites, "wherein the transgenic rat is a model for human HIV-1 binding". The specification as originally filed provides no implicit or explicit support for this recitation.

Applicant traverses this rejection. Applicant cites p. 2, line 32 -p 3, line 4 as supporting the instant recitation. This recitaion is not found persuasive because it discloses the general mechanism of CD4-gp120 binding. This would not be considered a disclosure of a transgenic rat that is model for human HIV-1 binding as claimed. From the specification, Applicant recites, " a nucleic acid encoding human CD4, or a portion thereof sufficient for binding to gp120..." as supporting disclosure of the above asserted new matter. This recitation from the specifcation would not be considered an implicit or explict disclosure of transgenic model for human HIV-1 binding because again this is disclosing a general mechanism of binding and not a rat that would comprise all the characteristics that would represent an animal model for human HIV-1 binding. Therefore, because Applicant's arguments are not found persuasive, and Applicant did not put forth amendments to the claims to address the new matter, the new matter rejection of record is maintained.